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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/708,918	11/08/2000	Julia J. Dibner	NVI-5009.1	2670

321 7590 05/30/2003

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/708,918	Dibner et al
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *May 5, 2003* .

2a) This action is **FINAL**. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *55-75* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *55-75* is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)	Notice of References Cited (PTO-892)	4)	Interview Summary (PTO-413) Paper No.s
2)	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5)	Notice of Informal Patent Application (PTO-152)
3) X	Information Disclosure Statement(s) (PTO-1449) Paper No.s: *14*	6)	Other:

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-5-03 has been entered.

2. Claims 55-75 are pending and under examination.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

4. It is noted that the specification at page 21 still contains embedded hyperlinks. The objection to the specification is maintained.

Information Disclosure Statement

5. The information disclosure statement filed 5-5-03 has been considered. See attached initialed copies.

Art Rejections

6. Claims 55-60 and 66-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al (WO 96/40233, published 12 December 1999).

Evans et al teach compositions for the in ovo vaccination of domesticated birds using *Eimeria* sporocysts. Evans et al teach that chickens vaccinated in ovo with herpesvirus of turkey Evans et al teaches that the sporocysts may be from two or more

species of *Eimeria* and include the species of *E. tenella, E. acervulina, E. maxima, E. necatrix, E. mitis, E. praecox* and *E. brunetti* can be used for in ovo vaccination of chicken eggs (page 4, lines 9-12). Evans et al teaches that the sporocysts may be from two or more species of *Eimeria* and include the species of *E. meleagrimitis, E. adenoeides, E. gallopavonis, E. dispersa, E. meleagridis, E. innocua* and *E. subrotunda* can be used for in ovo vaccination of turkey eggs (page 4, lines 15-19). Evans et al teach the sporocysts in suitable liquid carriers such as phosphate-buffered saline. Evans et al teach that the preferred dose is from 10^2 to 10^8 sporocysts per egg (see page 6, lines 25-30). Evans et al teach that contemplates that the preparation may optionally include one or more suspending agents including physiologically suitable gels, gelatins, hydrosols, cellulose or polysaccharide gums. Evans et al teaches that immune stimulants can be used in conjunction with the present vaccination and are preferably administered in the medium containing the dose of *Eimeria* sporocysts (see page 7, lines 9-17). Evans et al teach that the immune stimulants include cytokines, growth factors, chemokines, mitogens and adjuvants. Evans et al teach all the limitations of the instant claims. With respect to the limitation of "sanitized" it is noted that the sporocysts of Evans were prepared by substantially the same method as described in this specification. As such, the composition of live sporocytes described by Evans et al, inherently and necessarily meets this recited property.

The purification or production of a product by a particular process (i.e. the tangential flow filtration) does not impart novelty or unobviousness to a product when the product is taught by the prior art. This is particularly true, when the properties of the product are not changed by the process in an unexpected manner. *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983); and *In re Brown*,

173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular process, is unpatentable over the same product taught by the prior art. *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 559, 601, 38 USPQ 143-45 (CCPA 1938); and *United States v. Ciba-Geigy Corp.*, 508 F.supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

7. Claims 61, 62, 64, 71, 72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) in view of MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991).

Evans et al is set forth *supra*. Evans et al differs by not teaching the addition of preservatives to the vaccine composition.

MacDonald et al teaches vaccines for coccidiosis comprising live sporulated oocysts from different strains of *Eimeria* species and their use alone or in combination (column 5, last paragraph). MacDonald et al teach that there is little cross-species protection for different Eimeria species (column 2, lines 53-62). MacDonald et al teaches that the vaccines will comprise a suspension of the oocysts in "sterile distilled water" containing a suspending agent. MacDonald et al also teach that a preservative may be present to inhibit contamination with other organisms, e.g. formalin at a concentration of, for example 0.001% w/w (see column 7, lines 32-47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add a preservative according to MacDonald et al to the in ovo vaccine composition of Evans et al because MacDonald et al teach that it is desirable to add preservatives to vaccines to inhibit contamination with other organisms.

8. Claims 63, 65, 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (WO 96/40233; published 12 December 1999) and MacDonald et al (U.S. Patent No. 5,055,292, issued October 8, 1991) as applied to claims 61, 62, 64, 71, 72 and 74 above and further in view of Thaxton (U.S. Patent 5,311,841; issued may 17, 1994).

Evans et al and MacDonald as combined is set forth *supra*. The combination differs by not teaching the addition of growth stimulants and the combination with other vaccines.

Thaxton teaches a method for the delivery of medicaments to newly hatched poultry via intra-yolk sac injection. Thaxton teaches that the method of the invention provides a particular advantage in the treatment of coccidiosis in poultry and the method provides an effective vaccine for the treatment of coccidiosis and other vaccines that are available for a variety of poultry disease including fowl cholera, infectious bursal disease, Marek's disease etc (column 4, lines 30-59). Thaxton et al teach that the method of the invention is useful to provide medicants to newly hatched chicks by means of intra-yolk sac administration and that the medicants include vaccines, nutrients, antibiotics, probiotics, growth simulators ands sexual function modifiers. Thaxton teaches immunization of newly hatched chicks by means of intra-yolk sac injection (column 16, see Example 4) of sporulated oocysts for coccidiosis. Thaxton et al teach that the results indicate that intra-yolk sac injection and trickle treatment of sporulated oocysts provided useful protection to the chicks (see columns 19-20, bridging paragraph). Thaxton et al teach that the method and device is useful to deliver vaccines, antibiotics such as gentamicin, growth promoters and probiotics (see column 22-23, claims 2-11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the vaccine composition of Evans et al and MacDonald as combined *supra* by the addition of other medicants (growth promoters,

antibiotics and other vaccines) as taught by Thaxton et al because such a formulation would provide the expected benefits of preservation of the vaccine product, protection from more than one infection, promote and stimulate growth. One would be motivated to formulate the vaccines, antibiotics and growth simulators of Thaxton et al in combination with the vaccine of Evans et al and MacDonald et al as combined *supra* because such a formulation would provide the expected benefits of retarding bacterial growth that may occur, vaccination for coccidiosis and other avian diseases and certainly reduce trauma to the chicks by reducing the number of injections, reduce cost by eliminating multiple administration of different compositions and the formulation of the optimal amounts for the expected benefit(s) is well within the skill of the art. As such, the vaccine composition comprising live sporocysts, carriers, immune stimulants, growth promoters, preservatives and other avian vaccines is *prima facie* obvious over the art.

Pertinent Prior Art

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jenkins et al (Reference 11 on PTOL-1449 of 2-8-01) is cited to teach that "treatment with sodium hypochlorite removes contaminating bacteria (see page 75, column 1, Materials and Methods).

Status of Claims

10. No claims are allowed.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
May 28, 2003

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600